

that a biological deposit of wheat seed which, when grown would yield flour as claimed. In addition, the Examiner has argued that the deposit would only support enablement of claims directed to flour from progeny of the specific plants deposited. The Examiner argued that "no guidance" was provided for construction of any other plant used to make the recited flour. Applicants respectfully traverse the rejection.

First, Applicants note that a Petition for Suspension of Action under 37 C.F.R. § 1.103 accompanies this Response. Applicant will need at least 6 months to produce the required number of seeds of each of the parental lines expressly described in the application. Accordingly, Applicants respectfully request suspension of action for at least six months to propagate and deposit the appropriate seeds in a depository.

Second, Applicants respectfully submit that the full scope of claims 6-10 is enabled by the specification. As noted above, it appears that the Examiner believes that the full scope of the claims is not enabled by the specification **even with the requested deposit.**

Claim 6 is the broadest claim under examination and reads as follows:

Wheat flour obtained from endosperm of a seed of a plant which is modified to lack SGP-1, comprising wheat starch which has an apparent amylase content of about 35% or more.

To establish a *prima facie* case of non-enablement, the Examiner must show that undue experimentation would be required to make and use the claimed invention. Even if the practice of the claimed invention requires a considerable amount of experimentation, it is not necessarily "undue" experimentation:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) (citing *In re Angstadt*, 190 USPQ 214 (CCPA 1976).

MPEP § 2164.06.

The Examiner has presented no reason to explain why undue experimentation is required to practice the claimed invention. Accordingly, the Examiner

has not set forth a *prima facie* enablement rejection. To make the claimed flour, those of skill in the art merely have to generate a wheat plant modified to lack SGP-1 and then generate flour from the seeds of that plant. Applicants assume that the Examiner does not question that those of skill in the art know how to generate flour from wheat.

Generation of a wheat plant modified to lack SGP-1, at most, only requires routine methods well known to plant breeders of ordinary skill in the art. The Examiner has not explained why a plant breeder would have any difficulty in generating a plant lacking any gene encoding an active SGP-1 protein. The Examiner merely states that no guidance is provided regarding construction of any wheat plant having seed with an amylase content of 35 % or more. *See*, Office Action, page 7. This statement is simply not true. While the application points to specific exemplary wheat parental lines for generating such progeny, the application is generally directed to generating **any** wheat plant modified to lack SGP-1. The application teaches that any method that results in a wheat plant lacking SGP-1 can be used to make the claimed flour.

As the application teaches, wheat has a hexaploid genome and therefore has three pairs of chromosomes. *See*, page 3, line 30 of the present application. Each pair of chromosomes can carry an active SGP-1 allele. *See*, paragraph spanning pages 3-4 of the present application. The three pairs of chromosomes carry genes encoding SGP-A1, SGP-B1 and SGP-D1, respectively. SGP-A1, SGP-B1 and SGP-D1 are isozymes that are readily differentiated by SDS electrophoresis analysis. *See, id. citing* Yamamori and Endo, *Theor. Appl. Genet.* 93:275-281 (1996) (cited in IDS).

Generation of a wheat plant modified to lack SGP-1 entails simply identifying plants that lack an active copy of at least one of SGP-A1, SGP-B1 and SGP-D1 and then crossing the plants with plants that lack an active copy of a different gene selected from SGP-A1, SGP-B1 and SGP-D1 to create a wheat plant that lacks two of the active genes. *See, e.g.,* page 8, line 16 to page 10, line 13 of the present application. A wheat plant lacking the third gene of SGP-A1, SGP-B1 and SGP-D1 is then crossed to the progeny of the first cross to produce a plant without any active gene encoding SGP-A1, SGP-B1 or SGP-D1. *See, id.*

Those of skill in the art, reading the present specification, would understand that the application describes some wheat lines that have been identified to lack at least one SGP-1 gene. *See*, page 10, lines 3-13 of the present application. In addition, it is a simple matter to screen through additional wheat lines to identify those lacking at least one SGP-1 isozyme using SDS electrophoresis. As an alternative to screening currently available wheat lines, mutagenesis can also be used to generate wheat lacking at least one SGP-1 allele. *See, e.g.*, page 11, lines 5-23 of the present application. The Examiner has presented no reason to question the availability of parental wheat lines or creation of new lines that can be used to generate a wheat plant modified to lack SGP-1.

The Examiner states that "the claims are broadly drawn to all flour having an apparent amylase content of at least 35%." *See*, Office Action, page 7. It is not clear what relevance, if any, this has to the enablement rejection. Nevertheless, a reading of claim 6 reveals that the claim requires that the wheat flour is "obtained from endosperm of a seed of a plant which is modified to lack SGP-1." Thus, the claim does not read on all flour having an apparent amylase content of at least 35% as the Examiner states, but instead only encompasses wheat flour from a wheat plant which has been modified to lack SGP-1. If flour can be produced from wheat plants that do not lack SGP-1, that flour would not be encompassed by the claims.

As discussed above, Applicants will gladly deposit the seeds requested by the Examiner. However, the specification enables the full scope of the claims as filed. The Examiner has not pointed to any reason to question otherwise. Accordingly, Applicants respectfully request withdrawal of the rejection.

3. Written Description Rejection

Claims 6-10 were also rejected as allegedly claiming subject matter not described in the specification in such a way as to reasonably convey that the inventors were in possession of the claimed invention. According to the Examiner, to meet the written description requirement for a genus, a representative number of species must be

provided in the specification. The Examiner acknowledges that there are other ways to meet the written description requirement, but argues that they require description of the "complete structure" of the genus, which is impossible for plants. The Examiner further argues that it is not possible to describe the claimed products because there may be an infinite combination of parents that can provide progeny that can produce the claimed flour. Moreover, the Examiner argues that one of skill would not have been able to predict all of the resulting phenotypes of plants that could produce the claimed flour. Applicants respectfully traverse the rejection.

The purpose of the written description requirement, as the Examiner acknowledges, is to insure that the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the invention at the time the application was filed. As discussed in the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1 'Written Description' Requirement:"

Possession may be shown by actual reduction to practice, by a clear depiction of the invention in detailed drawings which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention, on **by a written description of the invention describing sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention.**

The Revised Interim Guidelines specifically state that "[w]hat is conventional or well known to one skilled in the art need not be disclosed in detail." *See, Federal Register 71427-71440, 71435 (Vol. 64, No. 244).* The present application describes the relevant characteristics of the claimed invention, thereby meeting the written description requirement.

The present invention relies on the very simple genetic principle that the absence of a gene encoding an active enzyme SGP-1 results in plants that have seed with a high (greater than 35%) amylose content. The claims under examination are directed to flour from such plants. Thus, all that is necessary to describe the claimed genus are the

following elements: flour, wheat, SGP-1 and amylose. While it is impossible to "completely" describe a plant, it is clear that those of skill in the art would not question that "flour" or "wheat" are readily recognized in the art. Similarly, it is readily understood what amylose refers to and how to measure its quantity. *See*, paragraph spanning pages 6-7 of the specification.

Finally, the SGP-1 enzyme and methods for its detection have previously been described in the art. *See*, Yamamori and Endo, *Theor. Appl. Genet.* 93:275-281 (1996), cited on pages 3-4 of the present application. Moreover, as discussed in detail above, the application sets forth a number of ways by which plants modified to lack SGP-1 can be created. Plants lacking various SGP-1 isozymes are readily identifiable. Thus, those of skill in the art would readily understand from the specification that the inventors had possession of the full scope of the claimed invention.

The Examiner states that the relevant analysis of written description is whether the application describes the phenotype of the plant from which the flour is derived. *See*, Office Action, page 5. The Examiner states that "millions of phenotypes" are encompassed by the claims and so are not adequately described. It is not completely clear to what the Examiner refers. It is true that the wheat plants modified to lack SGP-1 can vary greatly in their overall genotype. For example, the disease resistance of such plants could vary greatly. This fact is not relevant to the written description analysis. It is always true that "comprising" claims can include additional aspects (i.e., "millions" of different aspects). Nevertheless, if the relevant characteristics of the claimed invention are clearly described in the specification, and they are in this case, then the written description requirement has been met.

Though it does not appear to be relevant to a written description analysis, the Examiner further states that the claims may read on naturally occurring wheat plants that contain null alleles. *See*, Office Action, page 6. As indicated in the application on the paragraph spanning pages 7-8, the term "modified" in the claim refers to plants that are artificially modified and is intended to exclude naturally occurring plants. Moreover, as recited on page 4, lines 1-4 of the present application, no wheat plant has been

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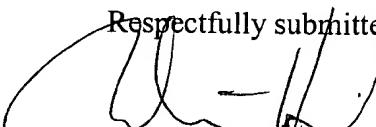
identified that lacks all three of SGP-A1, SGP-B1 and SGP-D1. Given the hexaploid genome of wheat, it is highly unlikely that all three genes would be homozygous null without human intervention. Applicants invite the Examiner to cite a discovery of such a naturally-occurring wheat plant. In any case, such analysis is not relevant for a written description analysis.

Accordingly, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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